ISSUANCES

of the

Meat and Poultry Inspection Program

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CONTENTS

UNITED STATES DEPARTMENT OF AGRICULTURE
Food Safety and Quality Service
Meat and Poultry Inspection Program
Washington, D.C. 20250

MEAT AND POULTRY INSPECTION (MPI)
PUBLICATIONS

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October 20, 1977

[3410-37]

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

[9 CFR Parts 317 and 319]

STANDARDS AND LABELING REQUIREMENTS FOR TISSUE FROM GROUND BONE

AGENCY: Food Safety and Quality Service, Meat and Poultry Inspection, U.S. Department of Agriculture.

ACTION: Proposed rulemaking.

SUMMARY: This document sets forth a proposed definition (including parameters for measuring compliance), permitted uses, and labeling requirements for a meat food product prepared by mechanical processing of tissue from ground bone. This proposal is based on new information, data, and arguments submitted to the Department in response to the April 27, 1976, proposal regarding mechanically deboned meat, as well as recommendations from a select Panel on Health and Safety Aspects of Use of Mechanically Deboned Meat and information and data available to the Department prior to publication of the first proposal.

DATE: Comments must be received on or before December 5, 1977.

ADDRESS: Any person wishing to submit written data, views, or arguments concerning the proposed rules may do so by filing them in duplicate with the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250. All such submissions made pursuant to this notice will be made available for public inspection in the Office of the Hearing Clerk during regular hours of business. Comments on the proposal should bear a reference to the date and page number of this issue of the FEDERAL REGISTER.

FOR FURTHER INFORMATION CONTACT:

Irwin Fried, Product Labeling and Standards Staff, Food Safety and Quality Service, U.S. Deparmtent of Agriculture, Washington, D.C. 20250, area code 202-447-6042.

SUPPLEMENTARY INFORMATION:

THE FIRST PROPOSAL

On April 27, 1976, the Administrator published a notice of proposed rulemaking titled "Definition of Meat and Classes of Meat, Permitted Uses, and Labeling Requirements." It appeared in Vol. 41, No. 82, pages 17560-17566 of the FEDERAL REGISTER with a comment period which closed on August 25, 1976. That proposed rulemaking included, among other things, a proposal for the permitted manufacture of "Mechanically Deboned Meat" and related products.

As proposed, these materials were defined as the product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle tissue. The proposed parameters for the three classes are given in Table 1.

TABLE 1

Proposed names	Meat class	Maximum percent calcium	Minimum percent protein	Minimum percent essential amino acids or minimum protein efficiency ratio	Maximum percent fat
Mechanically deboned meat	7	0.75	14	2.5 or 33	30
Mechanically deboned meat for processing.	8	1.0	10	2.5 or 33	
Mechanically deboned meat for rendering.	9				

As the table shows, limits for Mechanically Deboned Meat were to be lower for calcium and fat and higher for protein than parameters for the other two classes. Mechanically Deboned Meat for Processing was to have a requirement for protein quality, as measured by PER or proportion of essential amino acids, that was equal to the requirements for Mechanically Deboned Meat. No nutritional parameters were to be set for Mechanically Deboned Meat for Rendering, which was not to be used as such in the formulation of meat food products. No limitation on amount used in products was proposed for Mechanically Deboned Meat, but Mechanically Deboned Meat for Processing was to be lmited to 20 percent of the total meat, meat byproducts, poultry products, or poultry meat content of the product. The proposal also specified those products in which Mechanically Deboned Meat or Mechanically Deboned Meat for Processing were to be permitted as ingredients.

COMMENTS ON THE PROPOSAL

More than 1,100 comments were received in response to the proposal for redefining meat. The great majority of these comments dealt, in whole or in part, with the three proposed classes of mechanically deboned product (hereafter referred to as MDM). Many of these comments were complex, dealing with more than one aspect of the proposed redefinition. Also, many approaches to the same basic questions were used by the different commenters, further adding to the complexity of summarizing the issues. Therefore, no attempt has been made to provide exact tallies of the number of people commenting on any one issue in the discussion of that issue.

A general description of the comments and their sources follows:

Total comments	1100
Based on review of the proposal	175
Based on reports from secondary sources	925
From consumers (includes 13 organizations)	975
From industry (includes 17 trade groups)	80
From government agencies (Federal, State, local)	15
From university and college faculty	20
From health professionals (MD, RN, and OD primarily)	10

Of the 860 comments specifically addressed to the question of whether or not MDM should be allowed to be prepared and used in other products, 355 were yes and 505 were no. Many of these comments were based on reports in the news media rather than on readings of the proposal itself.

Of the comments based on readings of the proposal itself, consumers generally questioned the proposal, while others favored it. Comments by consumers fell into the following broad categories:

1. *Labeling.*—Concern was consistently expressed that if MDM was used, its presence should be identified in ingredients statements on product labels, so that the consumer could have knowledge needed to select or avoid such products as desired. Many of the concerns about labeling were tied to another concern, that of economics.

2. *Economics.*—Because there is a potential for the eventual use of one billion pounds of MDM yearly, consumers believed there would be a definite economic impact. They wanted savings, if any, passed on to them.

3. *Health.*—Issues related to health and safety aspects of use of MDM were of primary importance to consumers. Their concerns fell into the following categories:

a. *Bone.*—What effects would the amount of calcium permitted in MDM, the size of bone particles, and the digestibility of the calcium in bone have on calcium-related diseases and disorders such as diverticulitis?

b. *Trace elements.*—To what extent would there be problems of health and safety because of the presence or absence in bone of trace elements such as lead, fluorine, strontium-90, iron, nickel or zinc, and chemical and pesticide residues? Would any of these constituents be present in product containing MDM in amounts great enough to have toxic effects? Would any be helpful in improving nutrition?

c. *Lipids.*—Would there be changes in the amounts and kinds of fat in meat food products if they contained MDM? If so, would these changes be harmful to persons eating these meat products?

d. *Microbiological safety.*—Would meat food products containing MDM carry higher bacterial loads than meat food products without MDM? Should there be limits to the amounts of bacteria allowed in MDM?

Comments which were based on direct readings of the proposal, and which favored it, gave the following reasons:

1. The calcium contained in MDM is digestible and would be a useful addition to American diets.

2. The extra meat product so recovered would add a significant amount of high quality protein food to the world food supply.

3. Safety of the meat product recovered by this process need not be questioned because of the history of usage of mechanically deboned poultry (10–15 years) and mechanically deboned fish (20 years), and present usage of mechnically deboned red meat in approximately 40 countries throughout the world.

Industry spokesmen stated that proposed uses for MDM were too restrictive and should be expanded, both in permitted amounts and in the number of meat food products in which MDM could be used. Competition would see that if savings were realized, they would be passed on to the consumer.

Comments from industry also questioned the need for labeling other than species labeling (beef, pork, etc.) on the basis that there was no precedent for identifying the method of production in an ingredient statement, and mechanical deboning is a process resulting in a traditional ingredient. Specific labeling, according to some of these comments, would result in higher costs. Most health professionals and university faculty, on the other hand, favored either specific labeling of MDM in ingredient statements, or labeling for calcium content of final products, or both.

Comments from several consumer oriented organizations and Government agencies showed concern over whether or not use of MDM would result in adulteration, particularly if specific labeling of MDM in ingredient statements was not required.

A number of comments from industry and university faculty addressed themselves to technical aspects of the nutritional requirements for MDM (maximum contents of calcium and fat, and minimum requirements for amount and quality of protein). These comments were concerned not only with what the requirements should be, but also what measurements should be used to monitor these requirements.

Comments were also received concerning whether or not nutrition labeling should be required for products containing MDM and asking questions concerning flavor and texture of meat food products containing MDM.

The Interim Regulation

Also on April 27, 1976, in the issue of the Federal Register containing the proposed Redefinition of Meat, a regulation which included interim standards for MDM was published. The interim standards were to remain in effect pending final rulemaking on the proposal, unless rescinded before rulemaking was completed. The interim regulation was considered necessary in order to develop data, previously unavailable except on an experimental basis, for determining if the analytical parameters were effective in assuring nutritional quality of the products.

After the interim regulation was issued, a coalition of consumer oriented organizations and the Attorney General of Maryland took legal steps to have the interim regulation repealed. Following two court hearings, a Preliminary Injunction was issued on September 10, 1976, enjoining the Secretary from using the provisions of the interim regulation with respect to MDM. In the Court's opinion, the Department had not adequately assessed the potential health hazards of MDM in three areas:

(1) Possible gastroenterological side effects which may result from frequent ingestion of bone particles;

(2) The possibly unduly high levels of strontium-90 which may be contained in bone particles; and

(3) The possible long term effects of the fat content present in MDM on the cardiovascular systems of those Americans for whom processed meat products constitute a significant portion of their diets.

The Court further indicated that until such assessments were made, MDM was considered aadulterated and an adulterant. Following the September 10 Court Order, the Department ordered discontinuation of the placement of the official mark of Federal inspection on all MDM, which in effect stopped the production and use of it.

The Select Panel and Its Findings on Health and Safety Aspects of MDM

In order to respond to the questions on health and safety raised by the Court, an intensive analytical program was initiated to develop data on representative amounts of nutrients and problem substances in MDM. Samples for analysis were obtained from materials which had been commercially produced prior to the court ordered ban and had been maintained in frozen storage. The samples were analyzed in the laboratories of the Food Safety and Quality Service, using standard methods of analysis. To assure reliability of the procedures as applied to these samples, cross-check analyses for critical substances were made on some of the same samples by expert analysts in other Government laboratories.

To evaluate findings from this analytical program and pertinent information and data gathered from other sources, a panel of eminent Government scientists who are expert in a wide range of subject areas dealing with health and safety aspects of foods was convened.

Members of this group, hereafter called the Panel, were asked to respond to questions which had been raised both by the Court and in the comments on health and safety aspects of use of MDM. The summary of the Panel's conclusions and recommendations follows:

The Panel, after reviewing all pertinent data and information and the reports of the subcommittees, unanimously accepted those reports and drew the following conclusions and made the following recommendations:

A. Bone particle size as obtained with mechanical deboners currently available presents no hazards to health. However, the Panel recommended that limits for maximum particle size be included in any regulation to be promulgated allowing the production of MDM.

B. A slight nutritional benefit is to be expected for most people from the calcium in MDM, especially for persons whose customary intake of calcium falls below the Recommended Dietary Allowance. The calcium which would be added to the diet by MDM is not so great in amount as to pcse a hazard to the health of most people, except for those persons who are hyper-absorbers of calcium and likely already to be under medical supervision to limit their calcium intakes.

C. The fluoride content of MDM poses no health problem for adults. Fluoride intakes of children need to be controlled more closely than intakes of adults in order to avoid mottling of teeth. Since little is known about the fluoride intake of children, caution is advised. Data on projected consumption of MDM show that intakes of fluoride from MDM would be negligible, even for children consuming much higher than average quantities of MDM with a high fluoride content. MDM in the Panel's judgment presents no problem for children. However, fluoride intake of infants is known to be high. The Panel, therefore, concluded that prudence dictates that MDM not be incorporated into baby and junior foods at present. This recommendation is based primarily on lack of information rather than evidence of a hazard and should be subject to further evaluation as data are gathered.

D. The Panel concurred with the subcommittee evaluation that, based on currently available data and relative to the magnitude of other environmental sources of lead, the amount of lead which would be provided by MDM is toxicologically insignificant for children and adults.

E. Amounts of cadmium in MDM are so small as to be not detectable by current analytical procedures, and are of no public health significance.

F. Selenium was judged not to be a health problem. There is no evidence to indicate that selenium concentrates in bone.

G. Increases in dietary intakes of strontium-90 from use of MDM would be negligible, amounting to about a one-percent increase in exposures which are already well below tolerable limits. MDM poses no health hazards in regard to strontium-90.

H. Cobalt, copper, iron, nickel, zinc, arsenic, and mercury pose no potential problems in relation to use of MDM. Consumption data indicate that MDM would probably provide about 1 percent of the expected daily intake of cobalt. Additional iron from MDM would be in the order of 2.5 percent of the total iron intake, and should be readily available to the body. Zinc content of MDM is essentially the same as zinc in hand-deboned meat, and use of MDM should not affect bioavailability of zinc from other dietary sources. Arsenic has not been found in mechanically deboned poultry, and poultry would be expected to have greater relative intakes of arsenic than red meat animals. Therefore, arsenic should present no problem in MDM. Mercury does not accumulate in bone.

I. Chlorinated hydrocarbon residues present no special problem in MDM, because if present in measurable amounts, they are found in quantities well below established tolerance or action limits.

J. Data presently available on the lipid spectrum of MDM show that it is comparable to the lipid pattern found in hand-deboned meats. However, because of concern over the general problem of excessive intakes of fat and their effect on health, the Panel recommended that limits be placed on the fat content of MDM, on the basis of good manufacturing practices, and that limits also be placed on the fat content of products in which MDM could be used.

K. Proposed standards for protein content and quality (PER) are reasonable. Efforts should be continued to find more rapid and economical methods for monitoring protein quality, to replace the cumbersome PER essay.

L. The microbiology of MDM presents no unique hazards and should not be a problem if good manufacturing practices and quality control programs are employed.

M. Tetracyclines accumulate in the bones of young animals, and a recent German study has found tetracyclines in calf bones. The amounts are such that even at the highest level found, residues in products made with MDM derived from calf bones would be within present permitted tolerance. The U.S. slaughters comparatively few calves, and it is unlikely that there will be calf MDM. Tetracyclines in older cattle and swine present no problem. Though it is apparent that the use of tetracyclines in calves is on the decline in the United States, controls should be established to assure that if MDM is prepared from calves it will not exceed established tolerances for such drugs.

N. The Panel agreed that MDM contained in food products should be so labeled in the ingredients statement, so that persons who must stringently restrict calcium intake could avoid these products. The Panel further agreed that there was no need for health or safety reasons to make nutrition labeling mandatory for products containing MDM, although nutrition labeling of all food products [redacted] should be encouraged.

O. The Panel recommended that efforts should be made to inform and educate health and medical professionals and the general public about dietary effects of use of MDM, especially in relation to calcium fluoride.

P. The Panel recommended that further research should be encouraged on MDM when it is again produced commercially. Suggestions for research are given in several of the subcommittee reports. (End of Panel's conclusions and recommendations.)

Single copies of the complete report of the Panel may be obtained without charge from the Office of Information, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250. The report is entitled, "Health and Safety Aspects of the Use of Mechanically Deboned Meat, Volume I. Final Report and Recommendations, Select Panel."

The Revised Proposal

Because of the large number of questions of substantive concern, the widespread interest, and the court activity which were generated by the proposal and the interim regulation allowing production of MDM, it appears that several changes are needed in the proposed regulation, and that it would be highly desirable to provide an opportunity for the public to comment further on the proposed rule. Therefore, a revised proposal is being issued for standards and labeling requirements for Tissue from Ground Bone.

The new proposal contains the following provisions:

1. The product would be named "Tissue from Ground Bone". This appears to be an accurate descriptive name for the product.

2. Tissue from Ground Bone would be classified as a meat food product rather than as a class of meat. This change is indicated because of the presence in Tissue from Ground Bone of bone marrow and of minerals such as calcium and fluoride, which minerals are present in larger amounts than found in the muscle and accompanying fatty tissue which have been traditionally defined as meat. The change is further indicated by the fact that the United States District Court for the District of Columbia has held that this product is not meat as traditionally defined. However, Tissue from Ground Bone would be a meat food product, which is defined under the Federal Meat Inspection Act as, "* * * made wholly or in part from any meat or other portion of the carcass * * *"

3. The number of classes of such product has been reduced from three to one. The classes originally designated as Mechanically Deboned Meat and Mechanically Deboned Meat for Processing have been combined. This was done because a single use limitation for Tissue from Ground Bone is being proposed making separate classes unnecessary.

4. The calculation of percent of essential amino acids will be in terms of total amino acids, rather than in terms of total protein. Also, data on the essential amino acid tryptophan will be excluded in making this calculation.

The change to calculating in terms of total amino acids follows recommendations of university and industry scientists, who state that greater accuracy can be achieved by this procedure than by calculating as percent of total protein. Tryptophan is present in small and relatively constant proportions that would have little effect on the total percentage of amino acids. Also, tryptophan must be detremined by a separate method from that used for the other amino acids, so deleting the requirement for its analysis would help control costs of measuring compliance.

5. A requirement has been added that size of the openings in the sieves, screens, or ports of the equipment used in processing Tissue from Ground Bone should be no greater than 0.5 mm. in diameter.

This change follows the recommendation of the Select Panel that quality control measures be instituted in order to limit particle size to those levels presently associated with good manufacturing practice.

6. The requirements for minimum protein and maximum fat for Tissue from Ground Bone would be set at 14 percent and 30 percent respectively. These limits compare with minima of 14 percent and 10 percent for protein, and maxima of 30 percent and no limit for fat proposed for Mechanically Deboned Meat and Mechanically Deboned Meat for Processing, respectively. Tissue from Ground Bone thus compares with Mechanically Deboned Meat in that it has the same minimum protein content and the same maximum fat content but, as is discussed in 9 below, the same limit on usage in finished products as did Mechanically Deboned Meat for Processing. The Panel, in its deliberations, was reluctant to approve a product that would increase the total fat composition of meat products in which it was used. We believe that the proposed limitations satisfy the concerns of the Panel, especially since large portions of the meat diet, such as frankfurters, hamburger and ground beef, and beef sausage, are limited to 30 percent fat levels.

A 14 percent protein requirement on Tissue from Ground Bone with a 30 percent fat level precludes adulteration with water.

7. The provision that would allow Tissue from Ground Bone to be labeled by species only (beef, pork) rather than as a specific ingredient has been deleted. The species name would be used only in the ingredient statement and the term "Tissue from Ground Bone" would be used in conjunction with the product name.

The change to specific labeling follows the Panel's recommendation that food products containing Tissue from Ground Bone should be so labeled in the ingredient statement, so that persons who must stringently restrict calcium intakes could avoid these products. Specific labeling was also overwhelmingly desired by consumers and health professionals who commented on the original proposal.

8. Tissue from Ground Bone would not be allowed in baby (strained), junior, or toddler foods.

This change follows the recommendation of the Select Panel, which concluded that prudence dictates that Tissue from Ground Bone should not be incorporated into baby, junior, and toddler foods at present. This recommendation was based on lack of information rather than evidence of a hazard. The Panel's concern was that fluoride intakes of infants from birth to six months were known to be high, that long term data on the fluoride content of Tissue from Ground Bone are not available at present, and that the fluoride content of Tissue from Ground Bone may vary in different localities and may also depend on the age of the animal from which it is produced.

It should be noted that the Panel's concern for controlling fluoride intakes of infants was based not on a possible health hazard, but on the possibility of development of mottling of the teeth. Mottling can occur at much lower levels of fluoride intake than are required to develop fluorosis. Thus, controlling intakes of fluoride at levels which do not permit the development of mottled teeth would automatically insure that fluoride intakes stayed far below levels at which they were a health hazard.

Consumption studies reviewed by the Panel showed that projected increases in fluoride intakes from use of Tissue from Ground Bone would be negligible for all infants and children (ages 0 to 18 years), even at the top one percent level of consumption. Thus, the Panel concluded that it was not necessary to further restrict the use of Tissue from Ground Bone for reasons of safety. The Panel also indicated that the restriction on baby, junior, and toddler foods should be subject to further evaluation as data are gathered.

9. A limit of usage for Tissue from Ground Bone in any product would be set at 20 percent.

The original proposal set a use limit for Mechanically Deboned Meat for Processing of no more than 20 percent of the meat block (total of all meat, meat byproducts, poultry products and poultry meat) used in the formulation. No use limit was set for Mechanically Deboned Meat. The interim stand-

ard had stricter limits, permitting Mechanically Deboned Meat for Processing to make up no more than 15 percent, and Mechanically Deboned Meat no more than 20 percent, of the meat block of formulated products. Developmental research had showed that finished products retaining characteristic sensory qualities could be prepared with about 20 percent of the meat block as Tissue from Ground Bone, so these limitations on tissue were judged to be reasonable for purposes of data gathering. The limit is proposed to provide for caution in the introduction of this new product.

The need to proceed cautiously was emphasized by the evidence from analytical data that Tissue from Ground Bone is higher in content of fluoride and lead than is hand-deboned meat. A limitation of 20 percent Tissue from Ground Bone in the meat block was therefore built into calculations projecting the increased consumption of minerals from such tissue. The resulting consumption data were those used by the Select Panel in making its evaluation and recommendations. Safety at higher usage levels has been neither established nor disproved. Therefore, it has been concluded that permission for higher use levels would not be warranted at present.

10. Tissue from Ground Bone would not be allowed in ground beef, hamburger, fabricated steaks, barbecued meats, roast beef—parboiled and steam roasted, corned beef cuts, lima beans with ham and similar products, beef with gravy and gravy with beef, and meat pies.

The Department believes that inclusion of Tissue from Ground Bone in the above listed products would impair the basic characteristics of such products. For example, in most of these products, the consumer expects solid pieces of meat. In other cases (hamburger, ground meat, and fabricated steaks), the consistency normally expected by the consumer is significantly different than that contributed by Tissue from Ground Bone. These considerations led to a study by the Select Panel of consumption data. Its deliberations led the Department to propose the exclusion of these products. Expanding the usage of Tissue from Ground Bone to such products may require reconsiderations of the 20 percent usage level.

The proposed rule retains the following provisions from the earlier proposal:

1. The requirement for maximum calcium is set at 0.75 percent (the proposed maximum for class 7, MDM), and the minimum protein quality is set at a Protein Efficiency Ratio of 2.5 (the proposed minimum for classes 7 and 8, MDM and MDM for Processing).

Analytical data gathered after the first proposal was issued indicate that it is possible to routinely prepare Tissue from Ground Bone containing no more than 0.75 percent calcium. Furthermore, because significant and positive correlations were found between the content of calcium and the content of fluoride or lead in Tissue from Ground Bone, control of calcium may hold promise as a way of controlling content of these two potentially toxic elements. In addition, data gathered to date indicate that when calcium content of Tissue from Ground Bone is maintained at 0.75 percent or less, the protein quality (PER) is highly likely to equal or exceed 2.5, the proposed minimum. Therefore, it is proposed that a maximum of 0.75 percent calcium in Tissue from Ground Bone shall be included in the standards for this meat food product.

It is also proposed to maintain the protein quality requirement of a minimum PER of 2.5 for Tissue from Ground Bone. This requirement was recommended by the Select Panel, along with the provisions for measuring PER discussed below in item 2. Requiring a minimum PER of 2.5 would assure a product of high protein quality, equal to the quality of the milk protein casein. In addition, data gathered since publication of the previous proposal indicated that Tissue from Ground Bone which meets this standard for PER can be routinely prepared when good manufacturing practices (especially control of calcium) are employed.

2. Use of the value of percent of essential amino acids as a measure of protein quality would be allowed as an alternate to use of the Protein Efficiency Ratio.

The Select Panel found the proposed standards for protein content and quality (PER) to be reasonable, but recommended that efforts should be continued to find more rapid and economical methods for monitoring protein quality, to replace the cumbersome PER assay. In response to these recommendations, it is proposed that the standard for protein quality should be based on the PER, and rat feeding tests should be the only recognized method of determining the PER; that following the effective date of these amendments to the regulations, an amino acid profile which had a minimum of 33 percent of the essential amino acids isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine should be accepted in lieu of data on PER; and that after the expiration of approximately 12 to 18 months following the effective date of these amendments, a decision will be made as to the continued use of the alternate method, based on all information available to the Department, including data furnished by meat processors.

3. No standards are being set for maximum microbiological content of Tissue from Ground Bone.

In its analytical programs, the Department has found no evidence whatsoever that there is any bacterial health hazard associated with Tissue from Ground Bone when handled in keeping with good manufacturing practices. Furthermore, there is evidence, from the experience of the State of Oregon with bacterial standards for ground meat that the standards were not effective in reducing bacterial content of the ground meat, that the standards were unfair to consumers, who might be led to believe they resulted in meat with a lower bacterial content and thus improved quality, and that the cost of enforcing the standards was not justified by the benefits derived.

The Department has strict sanitary requirements, and handling practices (including times and temperature at which processed and stored) are expected to be such that product would not be abused. Federal meat inspection regulations already in effect require operators of establishments to institute appropriate control programs to assure the maintenance of their establishments and the preparation, marking, labeling, packaging and other handling of their products are strictly in accordance with sanitary and other requirements of the regulations. Inspectors are knowledgeable about perishability of meat products, sanitation, and proper handling practices. The meat inspection regulations provide ample authority for reinspection as deemed necessary using appropriate means, which may include statistically sound sampling to assure a high level of confidence in the final evaluation of the product.

The Department uses in other products, and intends to use in Tissue from Ground Bone, microbiological data as a basis for assuring that processing procedures are maintained in such a manner as to produce wholesome food. Handling practices would be monitored on a continuing basis.

4. Product failing to meet the requirements for Tissue from Ground Bone could be used for rendering.

Because of health considerations discussed above, product failing to meet the requirements for Tissue from Ground Bone because of high calcium may only be used for the production of animal fats. Until such time as standards are set for the low temperature rendered product such product produced from Tissue from Ground Bone failing to meet the requirements for reasons other than high calcium may be used in the production of imitation products as well.

On the basis of all the foregoing, the following amendments to the Federal meat inspection regulations (9 CFR Parts 317 and 319) are proposed:

1. Section 317.2(j) would be amended by adding a new subparagraph (13) to read as follows:

§ 317.2 Labels: definitions; required features.

* * * * *

(j) * * *

(13) When any Tissue from Ground Bone described in 319.5 of this subchapter is used as an ingredient in the preparation of a meat food product the name of the finished product shall be further qualified by the phrase, "Tissue from Ground Bone Added." Examples of such label declarations are: "Pork Sausage—Tissue from Ground Bone Added"; "Frankfurter—Tissue from Ground Bone Added"; "Cooked Salami—Tissue from Ground Bone Added". Any phrase qualifying the product name shall be at least ½ the size of the product name. In addition, the ingredient statement shall include in proper order of predominance the tissue from ground (species) bone; e.g., Tissue from Ground Beef Bone.

* * * * *

§§ 319.2—319.4 [Reserved]

2. Sections 319.2, 319.3 and 319.4 would be reserved, and a new § 319.5 would be

added to the meat inspection regulations to read as follows:

§ 319.5 Standards for tissue from ground bone.

(a) Any tissue resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle, and subsequent straining through a screen, sieve, or port. The openings in such screens, sieves or ports shall not exceed 0.5 millimeter in diameter. The tissue resulting from the separating process shall not have a calcium content exceeding 0.75 percent; shall have a minimum protein content of not less than 14.0 percent with a minimum PER of 2.5 (except as modified in paragraph (e)(1) of this section), and a fat content of not more than 30 percent. Such tissue failing to meet the calcium requirements of this paragraph shall only be used in producing animal fats. Such tissue failing to meet any of the other requirements of this paragraph shall only be used in producing animal fats or, alternatively, may be used in the formulation of imitation products.

(b) [Reserved]

(c) [Reserved]

(d) [Reserved]

(e)(1) An essential amino acid content of at least 33 percent of the total amino acids present in Tissue from Ground Bone shall be accepted as evidence of compliance with the protein quality requirement set forth in paragraph (a) of this section. The percent of essential amino acid content is calculated as the sum of the precentages of isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine, divided by the percentage of total amino acids and multiplied by 100.

(2) A prerequisite for the production of Tissue from Ground Bone shall be a plant quality control system[1] that the Administrator finds meets the requirements of this section. Acceptance is based on the ability of the system to provide the controls and information necessary to assure that the product will meet the requirements described in § 319.5(a) and to enable establishment personnel and Program employees to monitor the system for effectiveness. As a minimum, the system shall include a written description of the methods used by the establishment to maintain the wholesomeness and uniformity of the raw ingredients used in manufacturing product, to control the blending of the raw ingredients, and to control the handling and processing of the raw ingredients and the finished product, and shall contain provisions for chemical analyses of the product to determine compliance with standards for the product. Analyses to verify basic finished product constituents of fat, protein, calcium, essential amino acid content, and protein efficiency ratio shall be performed by the operator of the establishment or its agent to assure that finished product will meet the requirements in § 319.5(a). Finished product samples shall be analyzed by a laboratory in accordance with methods prescribed in the current "Official Methods of Analysis of the Association of Official Analytical Chemists,"[2] or by other appropriate analytical procedures approved by the Administrator in each case.

3. A new § 319.6 would be added to the Federal meat inspection regulations (9 CFR 319.6) to read as follows:

§ 319.6 Limitations with respect to use of Tissue from Ground Bone.

(a) When the Tissue from Ground Bone described in § 319.5 of this Part is used as an ingredient in other meat food products, the finished product shall be labeled in accordance with § 317.2(j)(13) of this subchapter. Products required to be prepared from meat or meat byproducts of one species may contain Tissue from Ground Bone only of the species.

(b) Tissue from Ground Bone described in § 319.5 of this Part may constitute up to 20 percent of the meat portion of any meat food product except listed in paragraph (c) of this section.

(c) Tissue from Ground Bone described in § 319.5 of this Part may not be used in baby (strained), junior or toddler foods, ground beef, hamburger, fabricated steaks (319.15 (a), (b) and (d)), barbecued meats (319.80), roast beef—parboiled and steam roasted (319.81), corned beef cuts (319.100), lima beans with ham and similar products (319.310), beef with gravy and gravy with beef (319.313), and meat pies (319.500).

4. The second sentence of § 319.14(c) would be amended to read:

§ 319.15 Miscellaneous beef products.

* * * * *

(c) * * * Binders or extenders, Tissue from Ground Bone used in accordance with § 319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product's characteristics are essentially that of a meat pattie.

* * * * *

§ 319.100 [Amended]

5. Section 319.100 "Corned Beef" would be amended by adding the following immediately after the second sentence: "Tissue from Ground Bone may be used in accordance with § 319.6."

§ 319.105 [Amended]

6. Section 319.105 "Chopped Ham" would be amended by adding a new subsection (b)(10) to read as follows: "Tissue from Ground Bone used in accordance with § 319.6."

7. The first sentence of section 319.141 would be revised to read:

§ 319.141 Fresh pork sausage.

"Fresh Pork Sausage" is sausage prepared with fresh pork or frozen pork or both, and may contain Tissue from Ground Bone in accordance with § 319.6, but not including pork byproducts, and may be seasoned with condimental substances as permitted under Part 318 of this subchapter. * * *

8. The first sentence of § 319.142 would be revised to read:

§ 319.142 Fresh beef sausage.

"Fresh Beef Sausage" is sausage prepared with fresh beef or frozen beef, or both, and may contain Tissue from Ground Bone used in accordance with § 319.6, but not including beef byproducts, and may be seasoned with condimental substances as permitted under Part 318 of this subchapter. * * *

9. The first sentence of § 319.143 would be revised to read:

§ 319.143 Breakfast sausage.

"Breakfast Sausage" is sausage prepared with fresh and/or frozen meat; or fresh and/or frozen meat and meat byproducts, and may contain Tissue from Ground Bone in accordance with § 319.6, and may be seasoned with condimental substances as permitted in Part 318 of this subchapter. * * *

10. The first sentence of § 319.144 would be revised to read:

§ 319.144 Whole hog sausage.

"Whole Hog Sausage" is sausage prepared with fresh and/or frozen meat from swine in such proportions as are normal to a single animal, and may include any Tissue from Ground Bone produced from the animal and used in accordance with § 319.6, and may be seasoned with condimental substances as permitted under Part 318 of this subchapter. * * *

§ 319.145 [Amended]

11. Section 319.145(a)(1) would be amended to read:

(1) "Italian Sausage" shall be prepared with fresh or frozen pork, or pork and pork fat, and may contain Tissue from Ground Bone in accordance with § 319.6.

12. Section 319.145(a)(2) would be amended by adding the following sentence immediately after the first sentence of that subparagraph: "Tissue from Ground Bone may be used in accordance with § 319.6."

13. Section 319.145(a)(3) is amended by adding the following sentence to the end of that subparagraph: "Tissue from Ground Bone may be used in accordance with § 319.6."

§ 319.180 [Amended]

14. The sixth sentence of § 319.180(a) would be revised to read: "Such products may contain raw or cooked poultry meat not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Tissue from Ground Bone used in accordance with § 319.6."

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[1] Send approval request to the Systems Development and Sanitation Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture (located at 14th and Independence Avenue SW.) Washington, DC 20250.

[2] Copies of this publication are available from the Association of Official Analytical Chemist, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

15. The seventh sentence of § 319.180 (b) would be revised to read: "These sausage products may contain poultry products, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Tissue from Ground Bone in accordance with § 319.6."

16. The second sentence in § 319.180 (c) would be changed to read: "When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name, e.g., 'Beef Frankfurter', and when such sausage products are prepared in part with Tissue from Ground Bone in accordance with § 319.6, they shall be labeled in accordance with § 317.2(j)(13) of this subchapter."

§§ 319.104, 319.182, 319.260, 319.261, 319.280, 319.281, 319.300, 319.301, 319.305, 319.306, 319.312, 319.760 [Amended]

17. The following sentence would be inserted immediately after the first sentence of each of the following sections: §§ 319.104(f) Pressed ham, spiced ham, and similar products, 319.182 Liver sausage and braunschweiger, 319.260 Luncheon meat, 319.261 Meat loaf, 319.280 Scrapple, 319.281(a)(1) Bockwurst, 319.300 Chili con carne, 319.301 Chili con carne with beans, 319.305 Tamales, 319.306 Spaghetti with meat balls and sauce, spaghetti with meat and sauce, and similar products, 319.312 Pork with barbecue sauce and beef with barbecue sauce, and 319.760(a) Deviled ham, deviled tongue, and similar products: "Tissue from Ground Bone may be used in accordance with § 319.6."

§§ 319.281, 319.302, 319.304, 319.307, 319.311, 319.600, 319.762 [Amended]

18. The following sentence would be added at the end of the following sections: §§ 319.281(a)(1) Bockwurst, 319.302 Hash, 319.304 Meat stews, 319.307 Spaghetti sauce with meat, 319.311 Chow mein vegetables with meat and chop suey vegetables with meat, 319.600(a) and 319.600(b) Pizza, and 319.762 Ham spread, tongue spread, and similar products: "Tissue from Ground Bone may be used in accordance with § 319.6."

19. Section 319.303 is amended by adding a new subsection (b)(9) to read:

§ 319.303 Corned beef hash.

* * * * *

(b) * * *

(9) Tissue from Ground Bone when derived from carcasses of cattle may be used in accordance with § 319.6.

* * * * *

NOTE: The Food Safety and Quality Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Done at Washington, D.C., on October 4, 1977.

ROBERT ANGELOTTI,
Administrator, Food Safety and Quality Service.

[FR Doc.77-29508 Filed 10-5-77;8:45 am]

(Pages 54437-54442)

Food Safety and Quality Service

[9 CFR Part 381]

POULTRY SLAUGHTERING PRACTICES

Notice of Proposed Rulemaking

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the poultry products inspection regulations by adding provisions containing new procedures and criteria for reprocessing poultry carcasses accidentally contaminated during slaughter with digestive tract contents. Recent information indicates that newer technology makes unsuitable present procedures that require the removal of internal contamination with digestive tract contents from carcasses by trimming only. The new procedures would permit the reprocessing of such contaminated carcasses by using various combinations of trimming, vacuuming, and washing, and then treating all surfaces of the carcasses with a chlorine solution.

DATE: Comments must be received on or before October 18, 1977.

ADDRESSES: Written Comments to: Hearing clerk, U.S. Department of Agriculture, Washington, D.C. 20250. Oral Comments to: Dr. J. P. Lyons, 202-447-3219.

FOR ADDITIONAL INFORMATION ON COMMENTS AND CONFIDENTIALITY SEE SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Dr. J. P. Lyons, Chief Staff Officer, Inspection Standards and Regulations Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C., 202-447-3219.

SUPPLEMENTARY INFORMATION:

Comments

Interested persons are invited to submit comments concerning this proposal. Written comments must be sent in duplicate to the Hearing Clerk. Comments should bear a reference to the date and page number of this issue of the Federal Register. Any person desiring opportunity for oral presentation of views must make such request to Dr. J. P. Lyons so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented. All comments submitted pursuant to this notice will be made available for public inspection in the Office of the Hearing Clerk during regular hours of business.

Background

Due to the nature of the evisceration process of poultry, an occasional spillage on edible tissue of digestive tract contents (opened crops, material from the vent and broken intestines, etc.) is unavoidable even when the best dressing techniques are used. The cleaning up of product so contaminated has evolved over the years into set patterns, each dependent upon the nature and location of the contaminant. Spilled digestive tract contents are permitted to be removed only by trimming, if found on the inside of the carcass or on an outside surface that has been cut. Spilled digestive tract contents are permitted to be removed by washing, if found on an uncut surface on the outside of a carcass. (Such practices are contained in a manual of instruction for inspectors—the Meat and Poultry Inspection Manual. These instructions may be viewed in the Office of the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. Additionally, copies will be provided free upon request to Dr. J. P. Lyons, Inspection Standards and Regulations Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250.) These practices appear to be authorized under section 6 of the Poultry Products Inspection Act (21 U.S.C. 455) which provides, among other things, that carcasses and parts which may be made not to be adulterated by reprocessing, need not be condemned and destroyed if reprocessed under the supervision of an inspector and thereafter found to be not adulterated.

Why Is This Proposal Needed?

It appears that the proposal would strengthen the regulations by spelling out specific procedures and criteria for reprocessing digestive tract contents. Also, the poultry industry believes that the recent availability of newer technology makes unsuitable the present policy that requires the removal of internal contamination with digestive tract contents from carcasses by trimming. This occasionally results in the unnecessary loss of carcass parts and consequent downgrading of product. The technology is essentially the reprocessing of such contaminated carcasses, first using various combinations of trimming, vacuuming and washing, and then treating all surfaces of the carcass with a chlorine solution. They point out that all losses due to unnecessary trimming and downgrading must eventually be borne by consumers. The proposed regulations would permit this type of reprocessing, but under strict inspection controls.

What Studies Were Made To Support This Change?

A recent USDA, Agricultural Research Service study found that it was possible to wash internally contaminated carcasses to the degree that their microbiological profile was equal to noncontaminated carcasses. In response to this research and following some feasibility studies, the Food Safety and Quality Service set up a study to see if equal results could be obtained by reprocessing carcasses internally contaminated with visible particles of digestive tract contents. This has been the historical criterion for disposition of contaminated product by inspectors in poultry slaughter plants. Both of these studies may be viewed in the Office of the Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. Additionally, copies will be provided free upon request to Dr. J. P. Lyons, Inspection Standards and Regulations Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Four broiler plants were selected for the test. A reprocessing station was set up in each plant. While not identical, they all had facilities for trimming, vacuuming, washing, and reinspection. During the test period, the usual procedure for reprocessing was one of trimming off all contaminated cut surfaces and fat, vacuuming, and internal washing. A variety of nozzles and spray heads were utilized, as were variations in water pressure and volume.

Following the reprocessing, carcasses were examined by a plant representative to assure that they were visually clean. During the test period, carcasses passed by the plant examiner were visually reinspected by inspection personnel. Additionally, 10 percent of the acceptable, visually clean carcasses were cut open and subjected to minute scrutiny by a USDA inspector to make sure that nothing was overlooked. The criterion used for the reinspection during the test was extremely tight—any visible speck called for rejection.

Analysis of the test results indicated that, when a carefully designed reprocessing procedure is applied with diligence by plant management, practically all contaminated carcasses can be reprocessed into an acceptable product without significant downgrading, and that the remainder of the carcass may be salvaged.

How Would the Inspection Service Control the Reprocessing?

Reprocessing of contaminated inner surfaces other than by trimming alone would be permitted only at reprocessing stations found by the Administrator to be capable of being operated in accordance with the poultry products inspection regulations and of providing operations capable of removing all visible specks of contamination on the inner surface of a carcass. This appears to be

necessary to assure that such reprocessing operations would be feasible and not contaminate other processing areas.

The inspection service would reinspect sufficient completed carcasses to assure that all visible specks have been removed. Carcass examinations and inspections that call for visual searches would be made without additional openings. Any visible particles would be cause for further reprocessing. All carcasses reprocessed under this program would be treated with chlorinated water at a level of 50 ppm before being returned to production. This would give additional assurance of product wholesomeness.

The proposal also contains provisions and criteria for the withdrawal of approval of a reprocessing station.

Accordingly, it is proposed to amend § 381.91 of the poultry products inspection regulations (9 CFR 381.91) by designating the first two sentences as paragraph (a) and by adding a new paragraph (b) to read as follows:

§ 381.91 Contamination.

* * * * *

(b) (1) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents shall not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not be be adulterated. Contaminated surfaces that are cut shall be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone, or at an approved reprocessing station, by any method that will remove the contamination, such as vacuuming, washing, and trimming, singly or in combination. All visible specks of contamination must be removed, and if the inner surfaces are reprocessed other than solely by trimming, all surfaces of the carcass shall be treated with chlorinated water at a level of 50 ppm.

(2) An area will be designated as an approved reprocessing station only if the Administrator determines that reprocessing operations can be conducted in that area in accordance with all of the requirements of this Part and that the reprocessing methods to be utilized are capable of removing all visible specks of contamination on the inner surface of a carcass. Requests for such approval shall be submitted to the Inspector in Charge and shall describe the proposed area, proposed methods of reprocessing, and proposed equipment to be utilized. Whenever the Administrator finds that reprocessing operations cannot be conducted in such area in accordance with all of the requirements of this Part or that the reprocessing methods utilized are not capable of removing all visible specks of contamination on the inner surface of a carcass, he may withdraw approval of such area, effective upon oral or written notification, whichever is earlier, to the operator of the establishment. In the event of oral notification, a written confirmation thereof shall be given to the operator as promptly as circumstances permit. The notification shall specify the reasons for such withdrawal and shall afford the operator of the establishment an opportunity to present his views. In any instance where there is a conflict as to the facts, a hearing shall be held to resolve such conflict.

NOTE: The Food Safety and Quality Service has determined that this proposal does not require preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Done at Washington, D.C., on August 16, 1977.

ROBERT ANGELOTTI,
Administrator, Food Safety and Quality Service.

[FR Doc.77-24123 Filed 8-18-77;8:45 am]

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

[9 CFR Part 381]

IMPORTATION OF POULTRY AND POULTRY PRODUCTS

Notice of Proposed Rulemaking

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes the addition of Israel to the list of countries from which poultry products of chickens, turkeys, ducks, geese, and guineas may be imported into the United States. Reviews of the export poultry inspection program of Israel indicate that it is acceptable under the Poultry Products Inspection Act.

DATE: Comments must be received on or before November 23, 1977.

ADDRESSES: Written comments to Hearing Clerk, U.S. Department of Agriculture, Washington, D.C. 20250. Oral comments to Dr. H. M. Steinmetz, 202–447–7610.

FOR INFORMATION ON COMMENTS, SEE SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT:

Dr. H. M. Steinmetz, Director, Foreign Programs Staff, Field Operations, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, Area Code 202–447–7610.

SUPPLEMENTARY INFORMATION:

Comments

Interested persons are invited to submit comments concerning this proposal. Written comments must be sent in duplicate to the Hearing Clerk. Comments should bear a reference to the date and page number of this issue of the Federal Register. Any person desiring opportunity for oral presentation of views must make such request to Dr. H. M. Steinmetz so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented. All comments submitted pursuant to this notice will be made available for public inspection in the Office of the Hearing Clerk during regular hours of business.

Background

Section 17 of the Poultry Products Inspection Act (21 U.S.C. 466) prohibits the importation into the United States of slaughtered poultry, or parts or products thereof, unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and unless they also comply with the rules and regulations made by the Secretary of Agriculture to assure that imported poultry or poultry products comply with the standards provided for in this Act. Section 381.196 of the regulations (9 CFR 381.196) provides that poultry inspection maintained by the foreign country, with respect to establishments preparing products in that country for export to the United States, must insure compliance of such establishments and their poultry products with requirements at least equal to all the provisions of the Act and the regulations that are applied to official establishments in the United States and their poultry products. In addition, for approval to export poultry and poultry products to the United States, the requirement that reliance can be placed upon certificates required under the regulations from authorities in the applying countries must also be met. Such articles from approved establishment in the countries listed in § 381.196 (b) are eligible for importation into the United States as provided in the regulations.

The laws and regulations of Israel concerning these matters have been reviewed and appear to be at least equal to the provisions of the Poultry Products Inspection Act and the regulations thereunder. Further, on-site reviews of the export poultry inspection program of Israel indicate that it is equal to our program in the United States. Certificates issued by Israeli officials for export of poultry products to the United States are reliable.

Accordingly, it is proposed that § 381.196(b) of the poultry products inspection regulations be amended to include Israel as a country which is eligible to import poultry products under Part 381, Title 9 of the poultry products inspection regulations.

Although a foreign country may be listed as approved for importation of poultry products under the Act and regulations, the poultry products of such foreign country must also comply with other Federal laws including restrictions under Title 9, Part 94 of the Animal and Plant Health Inspection regulations (9 CFR Part 94) relating to the importation of poultry and poultry products from foreign countries into the United States whose poultry flocks are infected with viscerotropic velogenic Newcastle disease (VVND). Section 94.6 of Title 9 (9 CFR 94.6) restricts the entry of poultry products into the United States from countries where viscerotropic velogenic Newcastle disease exists. Newcastle disease exists in Israel and, therefore, only those poultry products which meet the restrictions and conditions specified in § 94.6 actually will be allowed entry into the United States.

Note.—The Food Safety and Quality Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A–107.

Done at Washington, D.C., on September 15, 1977.

Dated: September 15, 1977.

Robert Angelotti,
Administrator,
Food Safety and Quality Service.

[FR Doc.77–27904 Filed 9–22–77;8:45 am]

[3410–37]

Food Safety and Quality Service

NITRATES AND NITRITES IN MEAT PRODUCTS

Statement of Policy, Request for Data

AGENCY: Food Safety and Quality Service, U.S. Department of Agriculture.

ACTION: Notice.

SUMMARY: The Administrator has determined that nitrates and nitrites as currently used in manufacturing cured meat products have the potential of interacting with components of the meat to form carcinogenic nitrosamines. As a result, he has established a program for obtaining from the industry information required to resolve definitive questions about the safety of the continued use of nitrites and nitrates in such products.

DATES: Data demonstrating whether the use of nitrates and/or nitrites in the production of bacon results in the formation of carcinogenic nitrosamines during its ordinary processing and/or preparation for eating shall be submitted on or before January 16, 1978. Data to demonstrate if carcinogenic nitrosamines are formed in cured products other than bacon as a result of ordinary conditions of processing and/or preparation for eating shall be submitted in accordance with the following time periods from date of publication of this document:

	Months
1. Dry cured cuts and fermented sausages, including dry and semi-dry sausages	6
2. Cooked sausages	12
3. Pickle cured products and perishable canned products	18
4. Shelf-stable and sterile canned products	24

ADDRESS: Send required information to: Hearing Clerk, U.S. Department of Agriculture, Wash., D.C. 20520.

FOR FURTHER INFORMATION CONTACT:

Irwin Fried, Acting Director, Product Labels and Standards Staff, Food Safety and Quality Service, U.S. Department of Agriculture, Room 202 Annex, Wash., D.C. 20250, 202–447–4293.

SUPPLEMENTARY INFORMATION: Selection of the above groups of cured products to be tested and their sequential listing on a priority basis is founded upon: (1) limited, but existing knowledge that carcinogenic nitrosamines have been found in several samples of these products; (2) limited national laboratory capability to simultaneously analyze all four categories of products; and, (3) the differing levels of nitrates and/or nitrites that are used in their production.

The finding of carcinogenic nitrosamines is not considered positive until confirmed by mass spectrometry.

Data to demonstrate that the use of nitrates and/or nitrites in the production of bacon does not result in the formation of carcinogenic nitrosamines during processing and/or preparation for eating shall be based on a cooking time of at least 3 minutes on each side and at a temperature of at least 340° F. Data made available to the Department since the publication of its proposed rule on nitrates, nitrites and salt (FR Vol. 40, No. 218, Tuesday, November 11, 1975, pp. 52613–52615) indicate that carcinogenic nitrosamines are being found in samples of bacon as prepared for eating.

Protocols to demonstrate whether carcinogenic nitrosamines are formed in cured products other than bacon as a result of ordinary conditions of processing and/or preparation for eating shall be submitted to the Administrator. As a minimum, the protocols shall include methods of processings and preparation for eating under ordinary conditions, sampling techniques and methods of analysis.

After review of all data now available to the Department and submitted pursuant to this notice the Administrator will determine the action to be taken to ban the use of nitrates and/or nitrites in the production of bacon and other cured products unless it is shown that the use of nitrates and/or nitrites will not result in the formation of carcinogenic nitrosamines in any samples of that product processing or preparation for eating.

The Administrator has determined that data requested may be submitted by industry associations or individual meat processing firms. The testing protocols are to be reviewed by the Administrator for assessing their sufficiency in providing the needed data.

Done at Washington, D.C., on: October 13, 1977.

ROBERT ANGELOTTI, Ph.D.,
Administrator, Food Safety and Quality Service.

[FR Doc.77–30430 Filed 10–17–77;8:45 am]

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
MEAT AND POULTRY INSPECTION PROGRAM
WASHINGTON, D.C. 20250

Meat and Poultry Inspection Manual

October 1977 **CHANGE:** 77-10

MAINTENANCE INSTRUCTIONS

Remove Page	Insert Page	Numbered
37 through 40	37 through 40b	77-10
255 and 256	255 and 256	77-10

Pen-and-Ink Changes

Page 74, section 11.5(i)(5)(iii), right column, last three lines, change to "23 to: Veterinary Services Laboratories, Pathology and Toxicology Laboratory, USDA, APHIS, P.O. Box 70, Ames, Iowa 50010."

Page 74a, first line, cross off "Maryland 20705."

Page 103, section 14.9, change the heading to read "UNBORN ANIMALS" and in line one change "calves" to "animals."

Page 140, section 18.24(d), right column, item 4, line 3, change "6.2 x 0.80" to "6.2 ÷ 0.80."

Page 231, section 22.24, second paragraph, add "main panel of" between the words "to" and "each."

Page 252, section 22.36(a)(1), line 5, change "67" to "31."

Page 253, section 22.36(a)(2)(i), line 5, cross off "MP Form 412-10."

Page 253, right column, line 1, cross off "and MP Form 414-4."

Page 209, MP Form 31, under "USE," cross off the words "to Germany."

MPI Directive 903.2, Exhibit C, change "Old Rates" to $9.96 for Base and $13.20 for Overtime and Holiday and "New Rates" to $10.64 for Base and $14.12 for Overtime and Holiday. The effective date for "Old Rates" is 10-24-76 and 10-9-77 for "New Rates."

If product contamination occurs as result of bag breakage, product must be rewashed immediately by spraying. All traces of refrigerant must be removed before product is passed for food. If all contamination cannot be removed by washing or trimming, affected portion must be condemned.

8.43 DRY ICE

When product is stored or shipped, dry ice (solid carbon dioxide) may be applied directly to it, used as an adjunct to, or as a substitute for refrigeration.

Precautions. High levels of carbon dioxide are harmful and may produce unconsciousness.

To assure that dry ice does not constitute a safety hazard, management must:

1. Provide dry ice dispensers (snowing hoods) with mechanical ventilation to eliminate accumulated gas. To be effective, exhaust intakes should be near floor level.
2. As a warning, identify rooms or areas where dry ice or product with dry ice is stored.
3. Monitor processing rooms where dry ice is used to assure that carbon dioxide does not exceed the .5 percent (5,000 ppm) maximum level set by the Occupational Safety and Health Administration. This limit does not apply to coolers, freezers, or storage rooms. Measurements should be taken about 5 feet above floor level.

INSECT AND RODENT CONTROL

Subpart 8-G

(Regs: M-318; P-Subpart H)

Insects and rodents may transmit diseases to humans through food contamination. Thus, their presence in or around plants creates a public health hazard. They can be eliminated by preventing their breeding and entrance into plants.

8.46 RODENT HARBORAGE

Breeding or hiding places--manure piles, paunch and stomach contents, hog hair, feathers, trash, junk or unused equipment, etc.--are potential sources of insects or rodents and are prohibited.

(a) Local Cooperation

Plant management should solicit cooperation from adjoining property owners and from local health authorities to eliminate breeding or hiding places and to develop an insect and rodent control program.

(b) Facility Maintenance

Building and equipment harboring pests shall be repaired or replaced. Floors, walls, partitions, and ceilings shall be free of cracks, crevices and openings. They must be of tight-fitting material not permitting entrance and breeding of cockroaches or other pests. Areas tunnelled by rodents must be repaired with concrete, brick, or other rodent-proof material.

Floor drain strainers shall be effective and kept in place to prevent rodent entrance through drainage lines.

All openings should be screened to prevent entrance of flies, rodents, birds, etc.

8.47 INSECTICIDES; RODENTICIDES

(a) Use

The Office of Pesticide Programs, Environmental Protection Agency (EPA), requires that insecticides and rodenticides be used only for intended purpose according to label instructions.

See "List of Chemical Compounds" for approved materials.

Warning! Many insecticides or rodenticides are toxic. If inhaled, ingested, or absorbed through the skin they may cause serious illness.

(b) Responsible Person

Only licensed pest control operators or responsible plant employees, under inspector's supervision, may prepare, mix, and use approved insecticides or rodenticides.

(c) Storage

Insecticides and rodenticides shall be in an area acceptable to the inspector in charge, and under the supervision of responsible plant employee.

8.48 INSECTICIDES

(a) Sprays, Aerosols

* **(1) Residual.** Residual insecticides are effective over a long period of time when used in conjunction with sound sanitation and maintenance programs.
* They may be used in inedible product areas and outside premises according to instructions on the EPA registered label. Precautions must be taken to prevent insecticide mist or affected insects from entering edible product processing or storage areas through open doors, windows, or ventilating systems, etc.
* They may be used for a single crack and crevice treatment in edible product processing areas, warehouse areas where edible product, ingredient, and packaging material is stored in sealed containers, and in nonprocessing areas such as offices, maintenance areas, employee locker rooms, etc., according to instructions on the EPA registered label, provided the following conditions are met:
  a. Production operations are not conducted in the area at time of treatment.
  b. All exposed edible product and packaging materials are removed, covered, or stored in closed containers.
  c. Plant management informs the inspector in charge of the treatment schedule. The inspector in charge will determine the necessary degree of coverage by an MPI inspector based on past experience with the insecticide applicator and control exercised by plant management. The need for the presence of an inspector during the chemical application may be minimized if experience has demonstrated the reliability of plant management and insecticide applicator. When the inspector in charge does not assign an inspector to be present during treatment, he may require the plant to identify the proposed treatment sites in advance to permit review during an inspector's normal tour of duty. He may also permit the treatment sites to be recorded at the time of treatment for later review by the inspector.
  d. They are not used for area treatment such as misting or fogging, or for surface treatment such as floor-wall junctions in rooms where their use is restricted to crack and crevice treatment.
  e. When used in offices, locker rooms, welfare areas, etc., insecticides must be used so that they will not be transferred to employees' clothing or other materials that may contact product.
  f. Broken areas such as cracks in block walls or separations at adjoining surfaces (example: floor-wall junction) are enlarged sufficiently to permit deep delivery of the insecticide into the insects' nesting sites while minimizing surface contamination. Opening may also be made in internal

* hollow walls to permit fogging insects' nesting sites. Walls that show evidence of water seepage should not be treated internally until all such seepage is corrected. Residual insecticides may be used inside electrical panels, light switches, motor housings, and similar areas in which insects cannot otherwise be effectively controlled.
* g. After treatment, the areas are ventilated to remove insecticide odors, and the facilities and equipment are thoroughly washed with an acceptable detergent solution and rinsed with potable water to remove all traces of contamination.
* h. The treated cracks and crevices are sealed with appropriate material within a reasonable period of time after treatment. The inspector in charge may include major projects in a plant improvement program.
* If adherence to all above provisions does not result in elimination of the insect infestation, the inspector in charge may permit repeat treatments under the same provisions. However, he must continue to require sound construction, sanitation, and maintenance programs to avoid hazards related to chemical use.
* Requests by plant management for residual insecticide treatment programs not covered by this section must be submitted through the inspector in charge to SDS.
* The following residual insecticides may be used: Baygon, Carbaryl (Sevin), Chlordane, Chlorpyrifos (Dursban, Dowco 179), Diazinon, Dichlorovos (DDVP, Vapona), Dimethoate (Cygon), Dipterex, Fenthion (Entex), Kepone, Lindane, Malathion, Methoxychlor, Ronnel.

(2) Nonresidual. Nonresidual or "knockdown" insecticides kill insects only on direct contact. They may be used in edible product areas, provided exposed edible products are removed, covered, or stored in closed containers before spraying. Facilities and equipment must be thoroughly washed with an effective cleaning compound and rinsed with potable water after spraying. The following nonresidual insecticides may be used: Allethrins, Lethanes, Pyrethrins, Pyrethrum extract, SBP-1382 (Synthrin, NIA 17370).

Concentrations of 1 percent or less--alone or in combination--of the following synergists may be used with the above insecticides: Piperonyl butoxide, Piperonal bis [2-(butoxyethoxy) ethyl] acetal (Tropital), N-Octyl bicycloheptene dicarboximide (MGK 264), n-Propyl isome, Sulfoxide.

Synergist concentrations may be increased to a maximum of 5 percent when the insecticide is dispensed as an aerosol spray.

(b) Pellets, Powders

Flies, cockroaches, and other insects in livestock pens, poultry receiving areas, and other inedible product areas may be controlled with approved residual bait or powder material.

Powder or granular insecticides, except those marketed exclusively in labeled dispenser containers, must be of distinct blue or green color.

Care must be taken that baits are not ingested by livestock or poultry.

(c) Repellants

Compounds with di-n-butyl succinate are effective repellants and can be used for exterior door and window facings, near loading docks, and other outside areas.

(d) Gases

(1) Authorized fumigants. Fumigation with hydrocyanic acid, methyl bromide, or phosphine (from aluminum phosphide) gas is sometimes necessary to eradicate insects. Since these gases are extremely poisonous to man as well as

insects, permission for their use must be obtained from the inspector in charge, and a competent, experienced person must be placed in direct charge of the operation. The fumigant must be used according to label directions and the label must be registered with the Office of Pesticide Programs, Environmental Protection Agency.

Raw uncured products must be removed from the room before fumigating. Uncooked cured hams and bacon, and cooked sausage or packaged products need not be removed.

Hydrocyanic acid, methyl bromide, or phosphine gas may also be used to eradicate mites, skippers, beetles, and similar insects from infested cured hams or similarly cured products, provided the infested meat is removed and condemned after such treatment. Uninfested meat or product must be aerated for at least 48 hours before packaging or further processing.

(2) **Proprietary fumigants.** When compounds are prepared from one or more chemicals and their combination results in a gas, they are referred to as "proprietary" fumigants. Such fumigants must be authorized by STS-SS. Their labels must be registered with the Office of Pesticide Programs, Environmental Protection Agency, and must include directions for use in meat and poultry plants.

All edible products and packaging materials must be removed from rooms to be fumigated. Food contact surfaces must be rinsed with potable water before product is returned.

(3) **Room ventilation; test.** After fumigation, the room must be ventilated. An experienced fumigator must test the room for safety to insure the gas has been removed from the room, product surfaces, and equipment. Fumigant equipment must be so constructed and controlled as to prevent product contamination.

(e) Dispensers

Automatic insecticide dispensers may be used with residual or nonresidual insecticides, provided the requirements of section 8.48(a) are met.

8.49 RODENTICIDES

Use of rodenticides is a means of eliminating rodents. Other methods--rodent proofing of buildings, destruction of rodent harborages, maintenance of rodent-free zone around plants--should be used to prevent rodent entrance into buildings.

(a) Approved Rodenticides

The following rodenticides may be used: 3-(alpha-Acetonylfurfuryl)-4-hydroxycoumarin (Fumarin) and its sodium salt (Fumasol), Alpha-Naphthylthiourea (ANTU), 2-[(p-Chlorophenyl) phenylacetyl]-1, 3-indandione (Chlorophacinone, Rozol), Diphacinone (Diphacin) and its sodium salt, 2-Isovaleryl-1, 3-indandione (PMP, Valone), 2-Pivalyl-1, 3-indandione (Pival) and its sodium salt (Pivalyn), Prolin, Red squill, Warfarin [3-alpha-Acetonylbenzyl)-4-hydroxycoumarin] and its sodium salt.

In general, rodenticides may not be placed in edible product departments until operations have ceased for the day and all uncovered products are removed from the area. Strict account must be kept of the location and number of stations in the area and the floor plan layout must be approved by the inspector in charge. Rodenticides may not be placed in dry salt cellars. They may remain in areas containing sealed, packaged meats, but care must be taken to place them so as to prevent contamination of the meat.

All labels must be registered with the Office of Pesticide Programs, Environmental Protection Agency.

(b) Rodent Baits

Bait boxes and fountains, tracking powders, and other rodenticides must

be removed from edible product departments before operations are resumed. All bait supplies must be stored in a separate place designated by the inspector in charge.

(1) Dry baits. Cereal, or other vegetable meals or flours may be mixed with one or more approved rodenticides, provided that they are first mixed with a green or blue dye.

Whole or cracked grains, or flours or meals pressed into cakes or pellets that do not have characteristics of food products, may be used without the green or blue dye. To help the rodenticide to adhere to whole or cracked grain, two ounces of melted animal or vegetable oil may be mixed with each five pounds of grain.

(2) Liquid baits. If prepared according to label directions, liquid baits may be used in bait fountains, provided the solution has a distinct green color.

(3) Bait fountain. It must be similar to bottle-type containers used in poultry houses. Each fountain must be marked "rodent bait" and placed in a bait box.

(4) Bait box. It must be marked "rodent bait" and have a serial number and firm's or responsible individual's name. Each box must have sides, top and bottom closed, or capable of being closed or fastened, with openings only for rodent entrance and exit.

(5) Tracking powder. It may be used in all departments, provided it has a distinct blue or green color, processing operations have ceased, all exposed products have been removed, and its use does not create a nuisance. After the powder is removed, floors must be washed with an effective cleaning compound and/or rinsed with potable water to remove all evidence of the tracking powder before operations are resumed.

(6) Sticky Boards. Board strips with extremely adhesive resinous material can be used to capture rodents. Since the adhesive does not contain rodenticide, board strips may be used in all departments provided their use does not create a nuisance.

8.50 RODENT EVIDENCE

When pests enter an establishment, certain eradication methods and chemicals may be used.

(a) Ultraviolet Light

"Black Lights" or ultraviolet lights may be used to determine evidence and possible sources of product contamination.

Such lights cause rodent urine stains to fluoresce. However, certain substances--sodium and potassium salts, cleaning agents, etc.,--also fluoresce. Thus, fluorescence under ultraviolet light and without other evidence of rodent infestation is not sufficient.

(b) Immediate Action

(1) Suspension of operations. When rodent evidence is discovered in production or production-related area--processing room, ingredient storage area, cooler, or any area where meat or poultry product is accessible--the inspector shall stop operations and movement of any material into or out of the area, and shall require management to:

1. Examine all products, packaging materials, and containers for rodent damage or contamination.
2. Destroy or decharacterize rodent damaged or contaminated product, carcass, parts, packaging materials and containers, and any open dry ingredient container.
3. Remove accumulations of equipment, paper, or other debris providing harborage in involved area, and wash and sanitize all equipment.
4. Survey premises and outside areas; eliminate all suspected

harborages (outside premises, maintenance areas, etc); close all possible rodent access points, and arrange all dry storage material to facilitate cleaning.

(2) Resumption of operations. The inspector may allow operations to resume after all actions are successfully completed.

8.51 CONTROL PROGRAM

(a) Minimum Requirements

An effective rodent control program includes:

1. Written designation and authorization of a qualified individual to assume responsibility for the program.
2. Sealing all openings or holes serving as possible entrance points.
3. Elimination of any harborage inside or outside the plant.

2. Cartons may not bear the inspection legend and must be marked "not for human consumption - for export to U.K."

3. On USDA/FSQS letterhead stationery, issue the following statements, signed by an MPI veterinarian:

a. The offals are derived from abattoirs which are subject to Federal meat inspection;

b. The offals are derived from animals which have been in the United States of America for at least 28 days immediately prior to slaughter;

c. There has been no outbreak of foot-and-mouth disease in the United States of America during the previous 12 months.

(x) Casings. They must be:

1. Accompanied by a declaration on USDA letterhead stationery signed by an authorized veterinary officer stating that casings were cleaned and scraped.

2. Identified by approved label with inspection legend including an establishment number in the 3,000 series (Food Inspection Service). To be eligible for inspection mark, casings must be sanitarily handled and from official plants, or must be packed under Food Inspection Service.

3. Upon exporter's request, accompanied by MP Form 415-5.

(xi) Fats, oils.

1. Certification. Issue MP Form * 412-3. Original must accompany ship- * ments. Shipments arriving without * certificate will be refused entry. Include the following on the export certificate:

a. Location of tanks. For example, Port #3 or Starboard #2 shall be shown in the space for "Shipping Marks" and "Stamp Numbers." Tanks shall be identified again in the "No. Column" as P-3 or S-2.

b. For each tank, the estimated product weight shall be listed in the weight column. Such weight may be obtained from marine surveyor.

c. A statement of cleanliness should be made in the description column to read: "Tanks were inspected and found to be clean."

2. Requirements:

a. Ship tanks. They will be inspected and passed for cleanliness before product is loaded onto the ship. Marine surveyors will do this inspection under general inspector's supervision. To be acceptable, tanks must be clean, dry, and free of residues from previous cargoes.

b. Product from I.D. Service. When product is shipped from an Identification (ID) Service place, an inventory of federally inspected lard or rendered fats will be maintained. Records will include additions to and removals from each storage tank. Inspector should be able to estimate product amount in storage at any time. An inspection opening is required on each tank. Tank connection to any line will be broken by removal of a 1-foot section of pipe when tank is sealed. Transfer from tank to ship is permitted only through a line without other connections than to the tank. Product transfer may also be accomplished by use of tank trucks. Ship tanks shall be examined to assure they are empty before operations start. Loading will be done under continuous supervision of the inspector. If operations are interrupted for any reason, the hatch on the tank must be sealed. The seal must not be broken until operations are resumed.

c. Label. Approved label(s) bearing printed inspection legend with establishment number (317.2) will be attached to the export certificate. Establishment number will be in the 3,000 series for product shipped from an ID Service installation. One export stamp will be issued for each ship's tank. Stamps shall be attached to all hatches of filled tanks. Original export certificate and attached label(s) shall be delivered to the shipper, who shall deliver them to the chief officer of the vessel carrying the shipment. The chief officer shall present the certificate and label(s)

to the port health authority on arrival in UK.

d. Antioxidants. Edible fats and oils may contain antioxidants in the following amounts:

Propyl gallate, octylgallate, dodecylgallate, or any mixture of the three----------100 ppm
Butylated hydroxyanisole (BHA)-200 ppm
Butylated hydroxytoluene (BHT)-200 ppm
Any mixture of BHA and BHT-----200 ppm
Citric Acid----------100 ppm

When product contains antioxidants, the label must include a description of antioxidants, and maximum amount expressed in parts per million.

(3) Marking, labeling. UK recognizes the Federal meat inspection legend, with establishment number of producing plant, as being the "official certificate" for importation of product from the United States. Such legend must be as required by regulations (312.2), and must be affixed to all shipping cartons. For large containerized shipments (vans), it must be attached to the container. If the container holds product from more than one plant, it must bear an inspection legend from each official plant represented by the product inside. Legend or product label with inspection legend may be applied to containers at places outside official plants by using ID Service (R).

To comply with regulations (322.4), issue MP Form 412-3 and mark outside containers as required by Section 312.8 of the regulations.

(4) Prohibited importation. The following importations are prohibited:

a. Fresh pork/byproducts (except to U.S. military forces; 22.36(a)(2)(ii)).

b. Scrap meat. Meat consisting of scraps, trimmings, or other pieces (with or without bone) of such shape or in such condition as to afford insufficient means of identification with a definite part of a carcass.

c. Any carcass part chopped or minced with or without spices, cereal products, salt, flavoring, vegetables, or other ingredients.

Exception: Beef patties, flake steaks, fresh beef or pork sausage, etc., may be shipped to the military.

d. Heads without submaxillary lymph nodes.

e. Livers without hepatic lymph nodes. These nodes must be incised (R) and left attached to the livers. Livers not meeting this requirement will be rejected.

f. Boneless meat from calves less than 3 months old.

(5) Ports of Entry. Fresh, chilled, or frozen meats or byproducts may enter UK only through the following ports: Avonmouth, Cardiff, Dover (Eastern Docks), Felixstowe, Folkstone, Great Yarmouth, Grimsby, Harwich, Liverpool, London (Royal Group), London (Tilbury), Newhaven, Plymouth, Sheerness, Southhampton, and Tyne (North Shields).

Processed or canned products are permitted entry at all ports.

(b) Poultry Products

(1) Plant approval. Federally inspected plants desiring to export fresh poultry products to UK must apply to RD. MP Form 31 shall be used. In certifying such plants, RD will apply the same criteria used in certifying poultry plants for slaughter/cutup to West Germany. Plants certified for West Germany are considered certified also for UK and need not apply for additional certification.

Exception: Federally inspected plants may export cooked poultry without specific approval.

(2) Eligible product; certification.

(i) Fresh poultry. The definition of "fresh poultry" for UK includes frozen carcasses and cut-up poultry, and giblets. Carcasses must be fully eviscerated and not contain or be

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND QUALITY SERVICE
MEAT AND POULTRY INSPECTION PROGRAM
WASHINGTON, D.C. 20250

MEAT AND POULTRY INSPECTION REGULATIONS

OCTOBER 1977 **CHANGE:** 77-10

MAINTENANCE INSTRUCTIONS

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(§ 307.4(d)(3) continued)
such a request will result in overtime service at the start of the following day: Provided, That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisions of §307.6(b).

§ 307.5 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an * exporter shall pay the Food Safety and Quality Service $14.12 per hour per * Program employee to reimburse the Program for the cost of the inspection service furnished on any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, the fourth Monday in October; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall become a holiday.

§ 307.6 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed, at the rate established in § 307.5(a), in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour service rendered by each Program employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of a Program employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

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§ 350.5 Application for service.

Any person who desires to receive service under the regulations in this part for meat or other product eligible therefor under such regulations may make application for service to the Administrator, upon an application form which will be furnished by the Administrator upon request.

§ 350.6 Denial or withdrawal of service.

(a) If any person has applied for service for meat or other product not eligible therefor under the regulations in this part, or has failed to make proper application for service or to pay fees and charges due for service furnished or to be furnished to him under the regulations in this part, or if the service cannot be furnished to any person applying therefor because of lack of available inspectors or other administrative reasons, the service may be denied to such person by the Administrator until the condition justifying such denial is corrected.

(b) Service under the regulations in this part may also be denied to any person by the Administrator for such period as he may deem proper, if it is determined, after opportunity for hearing before a proper official in the Department, that such person has been responsible for any willful misrepresentation to the Department concerning any meat or other product for which service has been requested under the regulations, in this part, or that such person has been responsible for the use without authority, or the imitation, of any marks or certificates of Federal meat inspection on or with respect to any meat or other product, or has otherwise been responsible for any fraudulent or deceptive practice with respect to such service, or that such person has interfered with or obstructed any inspector in the performance of his duties under the regulations in this part, or attempted to do so. Pending final determination of the matter, the Administrator may deny or withdraw service without hearing in those cases where the public interests so require. In other cases prior to the institution of proceedings for denial of service under this paragraph, the facts or conduct which may warrant such action shall be called to the attention of the person involved, in writing, and he shall be given an opportunity to demonstrate or achieve compliance with all applicable requirements.

§ 350.7 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant of a statement as to the amount due.

(c) The fees to be charged and collected for service under the
* regulations in this part shall be at the rate of $14.12 per hour for base time, *
* $14.12 per hour for overtime including Saturdays, Sundays, and holidays, and *
* $21.32 per hour for laboratory service, to cover the costs of the service and *

(§ 350.7(c) continued)
shall be charged for the time required to render such service. Where appropriate, this time will include but will not be limited to the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

[23 F.R. 9982, Dec. 23, 1958, as amended at 32 F.R. 13115, Sept. 15, 1967; 35 F.R. 6856, Apr. 30, 1970]

PART 351-CERTIFICATION OF TECHNICAL ANIMAL FATS FOR EXPORT

AUTHORITY: The provisions of this Part 351 issued under secs. 203, 205, 60 Stat. 1087, 1090; 7 U.S.C. 1622, 1624.

SOURCE: The provisions of this Part 351 appear at 40 FR 58627, December 18, 1975.

DEFINITIONS

§ 351.1 Meaning of words.

Words used in this Part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 351.2 Terms defined.

When used in this Part, unless the context otherwise requires:

(a) "Department" means the United States Department of Agriculture.

(b) "Program" means the Meat and Poultry Inspection Program of the Food Safety and Quality Service of the Department.

(c) "Administrator" means the Administrator of the Food Safety and Quality Service of the Department, or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) "Circuit supervisor" means an employee of the Program assigned to supervise and perform official work in a circuit. Such employee is assigned by and reports directly to the Administrator or person designated by him.

(e) "Inspector" means an employee of the Program or a cooperating State.

(f) "Circuit" means one or more inspected plants assigned to a circuit supervisor.

(g) "Recognized State" means any State not designated in § 331.2 of this chapter.

(h) "Cooperating State" means any State cooperating under § 351.7 in administration of the regulations in this Part.

(i) "Inspection" means ante-mortem and post-mortem inspection by Program inspectors or inspectors of a Meat Inspection Service of a recognized State.

(j) "Animals" means cattle, sheep, swine, goats, horses, mules and other equines.

(k) "Technical animal fat" means animal fat eligible for exportation, or storage for exportation, in accordance with § 325.11 of this chapter.

(l) "Certified technical animal fat" means technical animal fat certified

(§ 351.5(c) continued)
shipping technical animal fat from the plant or facility and storing and exporting such technical animal fat, and a written description of the shipping, receiving, and inventory records maintained for technical animal fat.

(d) The Administrator will determine, on the basis of all information available to him, whether the arrangements at the plant or storage facility are such as will assure that certifications of technical animal fat will be correct, and, if so, will grant the application for certification service. An applicant will be given an opportunity to present his views prior to refusal of the service.

§ 351.6 Official number.

The Administrator will assign a certified technical animal fat plant number to each plant granted service. Such number shall be preceded by the letter "C" and be used to identify all certified technical animal fat prepared or stored by the plant.

§ 351.7 Administration of certification service program.

(a) The regulations in this Part shall be administered by the circuit supervisor for the jurisdiction in which is located the certified plant or plants for which application for certification service is made, and such assistants as may be necessary will be assigned by the Administrator.

(b) The Administrator may enter into a cooperative agreement with any recognized State for the conduct by State employees of any surveys, examinations, and other activities involved in the administration of the regulations in this Part. However, certifications under these regulations may be issued only by Program employees, as provided in § 351.3.

FEES

§ 351.8 Charges for surveys of plants.

Applicants for the certification service shall pay the Department for * salary costs at $14.12 per hour, travel and per diem allowances at rates * currently allowed by the Government Travel Regulations, and other expenses incidental to the initial survey of the rendering plants or storage facilities for which certification service is requested.

§ 351.9 Charges for examinations.

(a) The hourly fees to be charged and collected by the Administrator * shall be $14.12 per hour for examinations, as provided for in § 351.14, and * * $21.32 per hour for any laboratory service required to determine the eligibili- * ty of any technical animal fat for certification under the regulations in this part. Such fees shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith.

(b) Charges may also be made to cover the actual cost of travel and per diem allowance at rates currently allowed by the General Services Administration, and other expenses incurred by the Department in connection with such examinations and laboratory service.

FACILITIES AND OPERATIONS

§ 351.10 Facilities.

(a) Facilities for the preparation, identification, and storage of the technical animal fat to be certified shall be furnished and maintained by the certified plant in accordance with this section.

(b) The operator of the certified plant shall provide at the plant, rooms, compartments, and equipment needed to maintain the identity of certified technical animal fats and materials used in their preparation, and separation of such articles from other products. Such rooms, compartments, and equipment shall be conspicuously marked with the phrase "Certified Technical Animal Fat" whenever they contain these fats.

§ 351.11 Identification and separation of technical animal fats for certification and materials for use therein; removal of wrappers, etc.; cleaning of equipment.

(a) All technical animal fat to be offered for certification under this Part and materials to be used in the preparation of such fat, and all certified technical animal fat, shall be identified and kept separate from other products from the time of receipt at a certified plant and throughout processing or handling at such plant. All wrappers and packaging shall be removed from the source materials to the fullest extent practicable before the materials are rendered at the plant.

(b) If a plant's operations are within the provisions of § 351.14(b)(3), all equipment shall be cleaned before it is used for receiving, preparation, or storage of certified technical animal fats or material to be used in preparation of such fats. Such cleaning shall be done in such manner as to prevent contamination of such certified fats or source material with materials that are unacceptable under § 351.3.

§ 351.12 Circuit supervisor to be informed when plant operates.

The operator of each certified plant shall inform the circuit supervisor, in advance, when the plant's work schedule will include preparing technical animal fats for certification and identify the approximate days and hours when operations will begin and end.

§ 351.13 Inspectors to have access to certified plants at all times.

For the purpose of administering the regulations in this Part, inspectors shall have access at all times by day or night to every part of a certified plant.

§ 351.14 Processes to be supervised; extent of examinations.

(a) All processes used in the preparation of certified technical animal fats at any certified plant shall be subject to supervision by an inspector. Certified plants shall not prepare any technical animal fat for certification under the regulations in this Part, except in accordance with such regulations.

(§ 354.75 continued)

Each product for which inspection service is requested shall be so arranged so as to permit adequate determination of its class, quantity, and condition as the circumstances may warrant.

§ 354.76 Time of inspection in an official plant.

The inspector who is to perform the inspection in an official plant shall be informed, in advance, by the applicant of the hours when such inspection is desired. Inspectors shall have access at all times to every part of any official plant to which they are assigned.

REPORTS

§ 354.90 Report of inspection work.

Reports of the work of inspection carried on within official plants shall be forwarded to the Administrator by the inspector in such manner as may be specified by the Administrator.

§ 354.91 Information to be furnished to inspectors.

When inspection service is performed within an official plant, the applicant for such inspection shall furnish to the inspector rendering such service such information as may be required for the purposes of §§ 354.90 to 354.92.

§ 354.92 Reports of violation.

Each inspector shall report, in the manner prescribed by the Administrator, all violations of and noncompliance with the Act and the regulations in this Part of which he has knowledge.

FEES AND CHARGES

§ 354.100 Payment of fees and charges.

(a) Fees and charges for any inspection shall be paid by the applicant for the service in accordance with the applicable provisions of §§ 354.100 to 354.110, both inclusive. If so required by the inspector, such fees and charges shall be paid in advance.

(b) Fees and charges for any inspection service shall, unless otherwise required pursuant to paragraph (c) of this section, be paid by check, draft, or money order payable to the Food Safety and Quality Service and remitted promptly to the Service.

(c) Fees and charges for any inspection pursuant to a cooperative agreement with any State or person shall be paid in accordance with the terms of such cooperative agreement.

§ 354.101 On a fee basis.

(a) Unless otherwise provided in this Part, the fees to be charged and collected for any service performed, in accordance with this Part, on a fee basis shall be based on the applicable rates specified in this section.

(§ 354.101 continued)

(b) The charges for inspection service will be based on the time required * to perform such services. The hourly rate shall be $14.12 for base time and * * $14.12 for overtime or holiday work. *

(c) Charges for any laboratory analysis or laboratory examination of * rabbits under this part related to the inspection service shall be $21.32 per * hour.

§ 354.105 Fees for additional copies of inspection certificates.

Additional copies, other than those provided for in §§ 354.141, 354.142, and 354.143, of any inspection certificates may be supplied to any interested party upon payment of a fee of $2.00 for each set of five or fewer copies.

§ 354.106 Travel expenses and other charges.

Charges are to be made to cover the cost of travel and other expenses incurred by the Service in connection with rendering inspection service. Such charges shall include the costs of transportation, per diem, and any other expenses.

§ 354.107 Continuous inspection performed on a resident basis.

(a) Except as provided in paragraph (b) of this section, the charges for inspection of rabbits and products thereof shall be those provided for in § 354.101(b) when the inspection service is performed on a continuous year-round resident basis and the services of an inspector or inspectors are required 4 or more hours per day. When the services of an inspector are required on an intermittent basis, the charges shall be at the hourly rate provided for in § 354.101(b) plus the travel expense and other charges provided for in § 354.106.

(b) The applicant will be given credit when inspectors assigned to the applicant's official plant perform inspection for the Department of Defense on products accepted for delivery by the applicant to the Department of Defense. The amount of such credit will be based on a formula concurred in jointly by the Departments of Defense and Agriculture.

§ 354.109 Fees or charges for inspection service performed under cooperative agreement.

Fees or charges to be made to an applicant for any inspection service which differ from those listed in §§ 354.100 through 354.107 shall be provided for by a cooperative agreement.

§ 354.110 Disposition of fees for inspection made under cooperative agreement.

Fees for inspection under a cooperative agreement with any State or person shall be disposed of in accordance with the terms of such agreement. Such portion of the fees collected under a cooperative agreement as may be due the United States shall be remitted to the Service.

INSPECTION PROCEDURES; ANTE-MORTEM INSPECTIONS

§ 354.120 Manner of handling products in an official plant.

§ 362.5 Fees and charges.

(a) Fees and charges for service under the regulations in this Part shall be paid by the applicant for the service in accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rate of $14.12 per hour for base time, * $14.12 per hour for overtime including Saturdays, Sundays, and holidays, and * $21.32 per hour for laboratory service to cover the costs of the service and shall be charged for the time required to render such service, including but not limited to the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

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(§ 381.35 continued)
decision was correct. Review of such appeal determination, when requested, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

Subpart G-Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) Inspector's Office. Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) Facilities for ante-mortem inspection. Batteries, coops, or other facilities in which live poultry is presented for ante-mortem inspection shall be of such arrangement and construction, and shall be so placed with sufficient light provided so that the inspector can clearly see the birds to the extent needed to carry out an adequate inspection.

§ 381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5 1/2 hours after the beginning of scheduled operations.

(§ 381.47 continued)

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the basic workweek subject to the provisions of § 381.38: Provided, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of five consecutive 8-hour days Monday through Friday, excluding the lunch period; except those plants presently operating on an approved Tuesday through Satuday schedule shall continue on this schedule until such time as a change in ownership occurs, or they request and are granted a Monday through Friday work schedule; and further, except in the designation of State programs, the Department may depart from the Monday to Friday workweek in those cases where it would seriously handicap the Department in carrying out its function.

(d) (1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: Provided, however, minor deviations from a daily operating schedule may be approved by the inspector in charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: Provided, That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of § 381.39(b).

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an * exporter shall pay the Food Safety and Quality Service $14.12 per hour per * Program employee to reimburse the Program for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, the fourth Monday in October; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall be the holiday.

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